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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,909	05/09/2001	Jayanta Roy-Chowdhury	ENZ-55(CIP)PC	8638
21967	7590	07/13/2006	EXAMINER	
HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/171,909

Applicant(s)

ROY-CHOWDHURY ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Art Unit: 1644

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 96/39176) in view of Katz (US Patent 4,950,469). Applicants arguments have been considered and deemed not persuasive.

Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen (see claims 1-13, pages 12-14,40,41). Oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see specification, page 17, second paragraph). Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever (see specification, page 17, second paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent

autoantigen whilst Katz teaches that teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues wherein the streptococcal antigens would function as an autoantigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Chen et al. teach use of oral tolerance to prevent antibody responses causing autoimmune diseases and Katz disclose that anti streptococcal antibodies are involved in rheumatic fever and that neutralization of said antibodies could be used to treat said disease.

Regarding applicants comments, Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Regarding applicants comments about Chen et al., page 8, lines 12-14 and the term autoantigen, Chen et al. further state in lines 18-20 of said page that regarding the term autoantigen that *"The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals."* Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Thus the streptococcal antigen as per disclosed by Katz would constitute an autoantigen as per the definition of said term in Chen et al. Regarding applicants comments about "high dose feeding", the method of Chen et al. is not limited to a method of "high dose feeding". For example, in claim 1 of Chen et al., the autoantigen is administered at a dosage wherein the autoimmune disease is treated. Thus, the method of Chen et al. does not require "high dose feeding". Regarding the specification, Example 1, said example is not drawn to the claimed method (it does not use a bacterial antigen) and is therefore irrelevant to the invention under consideration. Said example also refers to a specific dosage range wherein said range is not the dosage encompassed by the term "large amounts of

antigen" as per Chen et al. It is also noted that none of the claims under consideration recite the administration of any particular concentration of antigen. Regarding applicants comments about Katz, said reference discloses that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800-1644

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Art Unit 1644